25. (Amended): A gelatin capsule containing enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

According to 37 CFR 1.121(c)(1)(ii), amendments to Claims 19 and 25 are shown on separate sheets marked up to show the changes and attached to this reply as Attachment 1.

As permitted under 37 CFR 1.121(c)(3) Applicants attach a clean version of the entire set of pending claims as Attachment 2.

Remarks

Claims 19 and 25 have been amended in response to issues raised by the Examiner. Entry of the amendments and reconsideration of the claims in view of the amendments and discussion infra are respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 19 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. The Examiner objects to the placement of the term "sufficient" in claims 19 and 25 as originally presented, allegedly because the claims as originally presented include elements not actually disclosed, thereby rendering the scope of the claims unascertainable. Applicants have amended the claims as suggested by the Examiner, thereby obviating the Examiner's rejection. Entry of the amendments and withdrawal of the rejection in view of the amendments are respectfully requested.

Defective Oath or Declaration

The Examiner has required Applicants to file a new oath or declaration because the original declaration allegedly failed to point out a specific error being corrected. A new declaration accompanies this response, specifically stating the error being corrected by the present reissue application. Entry of the new declaration is respectfully requested.

The Examiner has also found the originally presented declaration deficient because the present reissue application is allegedly a broadening reissue, and therefore must be signed by the inventors rather than the assignee. The Examiner has characterized the present reissue application as broadening in view of the increase in the upper limit of the dosage range recited in claims 19 and 25 of the present reissue application relative to claims 19, 31, and 38 of U.S. Patent #5,910,319. Applicants respectfully submit that the Examiner has incorrectly characterized the scope of the present reissue application as broadening relative to that of U.S. Patent #5,910,319.

The present reissue application is not a broadening reissue because the recited range of 60-120 mg base equivalent of fluoxetine is narrower than the broadest scope claimed in U.S. Patent #5,910,319. "[A] claim which has been *broadened in a reissue as compared to its scope in the patent* is not a broadened reissue claim if it is narrower than, or equal in scope to, any other claim which appears in the patent." (M.P.E.P. § 1412.03, emphasis in original). Claim 1 of U.S. Patent #5,910,319 contains no dosage range limitation. Claims 19, 31, and 38 of U.S. Patent #5,910,319 depend either directly or indirectly from Claim 1, and add the dosage range limitation of 20-100 mg base equivalent of fluoxetine. Claims 19 and 25 of the present reissue application have been presented in independent form and recite a dosage range of 60-120 mg base equivalent of fluoxetine, a range that Applicants respectfully submit is narrower than the scope of Claim 1 of U.S. Patent #5,910,319. As such, present claims 19 and 25 are not broadened reissue claims. Reconsideration and withdrawal of the characterization of the present reissue application as a broadening reissue and the requirement of a new oath or declaration signed by the inventors are respectfully requested.

Respectfully submitted,

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Eli Lilly and Company
Patent Division
P.O. Box 6288
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July 29, 2003

ATTACHMENT 1

19. (Amended): A formulation of [sufficient] enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropyl-methylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

25. (Amended): A gelatin capsule containing [sufficient] enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

ATTACHMENT 2

19. A formulation of enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

20. A formulation of Claim 1 administering about 80-90 mg base equivalent of fluoxetine.

21. A formulation of Claim 1 administering about 90 mg of base equivalent of fluoxetine.

22. A formulation of Claim 19 wherein the fluoxetine is present as fluoxetine hydrochloride.

23. A formulation of Claim 20 wherein the fluoxetine is present as fluoxetine hydrochloride.

24. A formulation of Claim 21 wherein the fluoxetine is present as fluoxetine hydrochloride.

25. A gelatin capsule containing enteric fluoxetine pellets sufficient to administer a dose of 60-120 mg base equivalents of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

26. A gelatin capsule of Claim 25, wherein about 80-90 base equivalents of fluoxetine are administered.

27. A formulation of Claim 19 containing the following:

Cores	
Sucrose - starch nonpareils, 30-35 mesh	100-150 mg
Fluoxetine layer	
Fluoxetine hydrochloride	100.5-100.8 mg
Sucrose	20-30 mg
Hydroxypropylmethylcellulose	10-15 mg
Separating layer	
Hydroxypropylmethylcellulose	4-12 mg

Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)	35-55 mg
HPMC	5-15 mg
Talc	Trace.

28. A gelatin capsule of Claim 25, wherein about 90 mg base equivalent of fluoxetine are administered.

29. A formulation according to Claim 19 wherein the formulation additionally contains pindolol.

30. A method of treating a patient suffering from depression, obsessive-compulsive disorder, bulimia, pain, obsessive-compulsive personality disorder, post-traumatic stress disorder, hypertension, atherosclerosis, anxiety, anorexia nervosa, panic, social phobia, stuttering, sleep disorders, chronic fatigue, Alzheimer's disease, alcohol abuse, appetite disorders, weight loss, agoraphobia, improving memory, amnesia, smoking cessation, nicotine withdrawal syndrome symptoms, disturbances of mood and/or appetite associated with pre-menstrual syndrome, depressed mood and/or carbohydrate craving associated with pre-menstrual syndrome, disturbances of mood, disturbances of appetite or disturbances which contribute to recidivism associated with nicotine withdrawal, circadian rhythm disorder, borderline personality disorder, hypochondriasis, pre-menstrual syndrome (PMS), late luteal phase dysphoric disorder, pre-menstrual dysphoric disorder, trichotillomania, symptoms following discontinuation of other antidepressants, aggressive/intermittent explosive disorder, compulsive gambling, compulsive spending, compulsive sex, psychoactive substance use disorder, sexual disorder, schizophrenia, premature ejaculation, or psychiatric symptoms selected from stress, worry, anger, rejection sensitivity, and lack of mental or physical energy comprising administering a formulation of Claim 19.

31. A method of Claim 30 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

32. A method of Claim 30 employing a formulation administering about 90 mg base equivalent of fluoxetine.

33. A method of Claim 30 wherein the fluoxetine is present as fluoxetine hydrochloride.

34. A method of Claim 31 wherein the fluoxetine is present as fluoxetine hydrochloride.

35. A method of Claim 32 wherein the fluoxetine is present as fluoxetine hydrochloride.

36. A method of Claim 30 employing a formulation containing the following:

Cores	
Sucrose - starch nonpareils, 30-35 mesh	100-150 mg
Fluoxetine layer	
Fluoxetine hydrochloride	100.5-100.8 mg
Sucrose	20-30 mg
Hydroxypropylmethylcellulose	10-15 mg
Separating layer	
Hydroxypropylmethylcellulose	4-12 mg
Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)	35-55 mg
HPMC	5-15 mg
Talc	Trace.

37. A method of Claim 30 of treating a patient suffering from pain, further comprising the coadministration of morphine, codeine or dextropropoxyphene.

38. A method of Claim 37 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

39. A method of Claim 37 employing a formulation administering about 90 mg base equivalent of fluoxetine.

40. A formulation of Claim 19, wherein the pellets further comprise a separating layer.

41. A formulation of Claim 40, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

42. A formulation of Claim 19, wherein the pellets further comprise a finishing layer.

43. A formulation of Claim 40, wherein the pellets further comprise a finishing layer.

44. A formulation of Claim 41, wherein the pellets further comprise a finishing layer.

45. A formulation of Claim 21, wherein the pellets further comprise a separating layer.

46. A formulation of Claim 45, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

47. A formulation of Claim 21, wherein the pellets further comprise a finishing layer.

48 A formulation of Claim 45, wherein the pellets further comprise a finishing layer.

49. A formulation of Claim 46, wherein the pellets further comprise a finishing layer.

50. A gelatin capsule of Claim 25, wherein the pellets further comprise a separating layer.

51. A gelatin capsule of Claim 50, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

52. A gelatin capsule of Claim 25, wherein the pellets further comprise a finishing layer.

53. A gelatin capsule of Claim 50, wherein the pellets further comprise a finishing layer.

54. A gelatin capsule of Claim 51, wherein the pellets further comprise a finishing layer.

55. A gelatin capsule of Claim 28, wherein the pellets further comprise a separating layer.

56. A gelatin capsule of Claim 55, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

57. A gelatin capsule of Claim 28, wherein the pellets further comprise a finishing layer.

58. A gelatin capsule of Claim 55, wherein the pellets further comprise finishing layer.

59. A gelatin capsule of Claim 56, wherein the pellets further comprise a finishing layer.

60. A method of Claim 30, wherein the pellets further comprise a separating layer.

61. A method of Claim 60, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

62. A method of Claim 30, wherein the pellets further comprise a finishing layer.

63. A method of Claim 60, wherein the pellets further comprise a finishing layer.

64. A method of Claim 61, wherein the pellets further comprise a finishing layer.

65. A method of Claim 32, wherein the pellets further comprise a separating layer.

66. A method of Claim 65, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

67. A method of Claim 32, wherein the pellets further comprise a finishing layer.

68. A method of Claim 65, wherein the pellets further comprise a finishing layer.

69. A method of Claim 66, wherein the pellets further comprise a finishing layer.

70. A method of Claim 30 without an increase in nausea.

71. A method of Claim 32 without an increase in nausea.

72. A method of Claim 36 without an increase in nausea.

73. A method of Claim 37 without an increase in nausea.

74. A method of Claim 38 without an increase in nausea.

75. A method of Claim 39 without an increase in nausea.

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JUL 31 2003
PATENT & TRADEMARK OFFICE

Docket No.: X-10709B
Application No.: 10/058,891
Filing Date: January 28, 2002

REISSUE DECLARATION BY THE ASSIGNEE, POWER OF ATTORNEY, AND SURRENDER OF PATENT

I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I am authorized to act on behalf of the following assignee: Eli Lilly and Company, and the title of my position with said assignee is General Patent Counsel.

The entire title to the patent identified below is vested in said assignee.

I believe Neil R. Anderson, Roger G. Harrison, Daniel F. Lynch, and Peter L. Oren are the original, first and joint inventors of the subject matter which is claimed and for which United States Patent No. 5,910,319 was granted on June 8, 1999 for the invention entitled

FLUOXETINE ENTERIC PELLETS AND METHODS FOR THEIR PREPARATION AND USE

the specification of which:

[X] is attached hereto
[ ] was filed on _____
as United States Application Serial No._____
or
PCT International Application No._____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. 1.56.

I believe the original patent to be wholly or partly inoperative or invalid, by reason of the patentee claiming more than he had a right to claim in the patent.

At least one error upon which reissue is based is described as follows:

The lower limit of the dosage range in Claims 19, 31 and 38 is too low, encompassing doses of less than 60 mg base equivalent of fluoxetine.

I state that the above-identified errors arose without any deceptive intention on the part of the applicants.

I surrender the above-identified letters patent which accompanies this paper and request that the letters patent be reissued to the said Eli Lilly and Company for the same invention upon the foregoing specification.

Power of Attorney: I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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Thomas E. Jackson	33,064	Alexander Wilson	45,782
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said Robert A. Armitage and Douglas K. Norman to have in addition the power to revoke the power granted to all others listed above.

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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